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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/828,892

04/20/2004

Michael T. Barrett

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AGILENT TECHNOLOGIES INC.

INTELLECTUAL PROPERTY ADMINISTRATION,LEGAL DEPT.

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EXAMINER

SALMON, KATHERINE D

ART UNIT

PAPER NUMBER

1634

MAIL DATE

DELIVERY MODE

05/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/828,892	Applicant(s) BARRETT ET AL.	
	Examiner Katherine Salmon	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 10-25 and 30-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 26-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is in response to the papers filed 2/27/2007. Currently Claims 1-33 are pending. Claims 10-25, 30-33 have been withdrawn as being drawn to a nonelected invention.
2. A complete reply to the final rejection must include cancellation of nonelected claims and subject matter or other appropriate action (37 CFR 1.144) See MPEP §821.01.
3. The following rejections to Claims 1-9, 26-29 are applied as necessitated by amendment or are reiterated. Response to arguments follows.
4. This action is FINAL.

Withdrawn Rejections

5. The rejections of the claims under 35 USC 102(b) and 35 USC 103(a) in view of Pinkel et al. made in sections 6 and 11 is moot based on the amendments to the claims.
6. The rejections of the claims under 35 USC 102(b) and 35 USC 103(a) in view of Brennan made in sections 7 and 12 is moot based on the amendments to the claims.
7. The rejections of the claims under 35 USC 102(b) and 35 USC 103(a) in view of Fodor et al. made in sections 8 and 13 is moot based on the amendments to the claims.

Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1-9, and 26-29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Upon review of the specification, the specification does not appear to provide support for recitation of "wherein said chromosome structural region oligonucleotide feature comprises an oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions of other chromosomes of said mammalian cell". In response of the amendment, applicants point to pages 11-12 as providing support for "wherein said chromosome structural region oligonucleotide feature comprises an oligonucleotide that specifically binds to a structural region of a single chromosome of a mammalian cell and does not specifically bind to structural regions of other chromosomes of said mammalian cell". However, the cited passages teach only arrays that comprise chromosome structural region oligonucleotides that bind to structural regions under stringent binding conditions, but these teachings do not provide support for the concept of an oligonucleotide feature that binds to only a structural region of a single chromosome and which does not

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specifically bind to a structural region of other chromosomes.

These amendments to the claims, therefore, constitute new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Bao et al. (US Patent Application Publication 2001/0018183 August 30, 2001).

With regard to Claims 1-3 and 6, Bao et al. teaches an array comprising DNA sequences from all human telomeres and all human centromeres (p. 10 paragraph 134). Bao et al. teaches an array comprising human telomeres and centromeres (mammalian cells) (p. 10 paragraph 134). Bao et al. teaches that these elements are unique sequence regions immediately adjacent to repeat sequence regions (p. 10 paragraph 134), therefore these sequences would specifically bind to only one chromosome (e.g., the chromosome with the unique sequence region).

With regard to Claim 4-5, Bao et al. teaches an array comprising all human telomeres and centromeres therefore, Bao et al. teaches a set of chromosome

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structural region oligonucleotide features for all chromosomes.

With regard to Claim 7, Bao et al. teaches an array which also comprises microdeletion syndrome regions (non-structural regions) (p. 10 paragraph 134).

With regard to Claim 8, Bao et al. teaches an array with centromeres and telomeres (structural regions) and microdeletion syndrome regions (non-structural regions) therefore the array would have at least one non-structural region interspersed with one structural region.

With regard to Claim 9, Bao et al. teaches an array comprised of target elements of centromeres and telomeres (structural regions) and microdeletion syndrome regions (non-structural regions) (p. 10 paragraph 134). Bao et al. teaches that target elements are regions of a substrate surface that contains immobilized nucleic acids (p. 3 paragraph 45). Therefore, the nonstructural regions and the structural regions are separated on the array since each represents a spot on the array, which represents a different target element.

Response to Arguments

The reply traverses the rejection. The reply asserts that Bao et al. fails to explicitly disclose an array containing oligonucleotides that specifically bind to a structural region of a single chromosome (p. 7). This argument has been thoroughly considered but has not been found persuasive. As discussed above Bao et al. teaches arrays comprised of unique sequences of centromeres and telomeres ((p. 10 paragraph

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134). These regions therefore would specifically hybridize to only the chromosome that possessed the unique sequence.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 26- 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bao et al. (US Patent Application Publication 2001/0018183 August 30, 2001) in view of Ahern (The Scientist July 24, 1995 Vol. 9 Issue 15 p. 20).

With regard to Claims 26-27, the recitation “for assessing chromosome copy number in a cell” has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Accordingly, the claim language of “for assessing chromosome copy number in a cell” merely sets forth the intended use or purpose of the claimed kits, but does not limit the scope of the claims.

With regard to Claims 26, Bao et al. teaches an array comprising DNA sequences from all human telomeres and all human centromeres (chromosomal structural features) (p. 10 paragraph 134).

With regard to Claim 27 -29, Bao et al. teaches labels that are applied to all nucleic acid populations such that the populations are labeled with different fluorescent markers (p. 4 paragraph 56 and p. 7 paragraph 96).

Bao et al., however, does not teach a kit.

Ahern teaches kits to deliver to researchers prepared chemicals (p. 1 last paragraph). Ahern teaches included in the kit is a sheet of instructions (Figure 1 p. 20 Hot seller, instruction sheet is in the background). With regard to the limitation that the kits contain instructions, the inclusion of instructions is not considered to provide a patentable limitation on the claims because the instructions merely represent a

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statement of intended use in the form of instructions in a kit. See In re Ngai, 367 F.3d 1336, 70 U.S.P.Q.2d 1862 (Fed. Cir. 2004)(holding that an inventor could not patent known kits by simply attaching new set of instructions to that product).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to incorporate the probes on the array of Bao et al. into a kit as taught by Ahern. The ordinary artisan would want to incorporate the probes and the array into a kit because Ahern teaches "remade biochemicals and reagents offer scientist the opportunity to better manage their time, putting these products all together in kits take the convenience one step further." (Ahern p. 24).

Response to arguments

The reply traverses the rejection. The reply asserts that Ahern et al. does not teach the deficiency of Bao et al. for a structural region specifically binding to a chromosome (p. 11). This arguments has been thoroughly reviewed but has not been found persuasive. As discussed in the response to arguments above, Bao et al. teaches an array comprised of unique sequences therefore these sequences would specifically hybridize to only the chromosome with that unique sequence.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

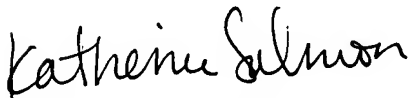
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Katherine Salmon
Examiner
Art Unit 1634


CARLA J. MYERS
PRIMARY EXAMINER